Application No.: 10/525,674 Docket No.: 13111-00002-US Amendment Dated November 3, 2006

Reply to Office Action of May 4, 2006

# **REMARKS**

Claims 1, 5, 7-12, 14, and 17-31 are pending. The claims have been amended or cancelled without disclaimer or prejudice. Support for the amendments is found *inter alia* in the original claims. Amended claim 1 finds support in original claims 1, 2, 4, 6, and 14, in the specification at page 2 lines 8-31 and page 5 lines 22-23, and in Example 8 at pages 37-38. The amendments to claims 10 and 11 find support in original claims 2, 10, and 11 and in the specification at page 2 lines 8-9. Claims 7-9 and 14 have been amended to better comply with U.S. practice. Claims 2-4, 6, 13, and 15-16 have been cancelled without prejudice or disclaimer. Non-elected claims and subject matter are cancelled without prejudice. New claims 17-31 find support in the original claims and in the specification at page 2 lines 8-31 and at page 7 line 21 through page 8 line 24. New claim 17 finds support in original claims 1, 2, and 3. New claim 24 finds support in original claims 1, 2, and 4. The new claims are consistent with the restriction requirement. No new matter has been added.

# **Objections To The Claims**

The Examiner objects to claims 4-6, 11-12 for comprising non-elected subject matter. In light of the amendments, this objection is believed to be rendered moot and is respectfully requested to be withdrawn.

### Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected for indefiniteness claims 5-6 for the term "homologous." Claim 6 has been cancelled without prejudice or disclaimer. Claim 5 as amended does do not recite "homologous." In view of the amendments, the rejection as to claim 5 and 6 is believed to be rendered moot and is respectfully requested to be withdrawn.

The Examiner rejected for indefiniteness claim 11 for the phrase "is at least particularly switched off." Applicants respectfully traverse. Claim 11 recites "partially" not "particularly" as asserted by the Examiner. Furthermore, support for the phrase is found in the specification at page 4 lines 1-5, page 15 line 35 through page 16 line 6, and page 20 lines 1-3. Reconsideration and withdrawal of this rejection is respectfully requested.

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# Rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1-12 and 14 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and for lack of an enabling disclosure. Applicants respectfully disagree and traverse the rejections for the following reasons.

#### Written Description

The Examiner argues that the specification fails to describe the claimed class of sulfur containing chemical or the claimed additional gene of the biosynthetic pathway, on the basis that the specification does not describe a representative number of species encompassed by the genus of the claimed class of sulfur containing chemical or of polynucleotides encoding metA protein. Applicants respectfully disagree and traverse the rejection. However, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer. As amended, the claims recite a specific sulfur containing chemical "L-methionine" and the L-methionine pathway (claim 10).

The applicable test for written description is stated in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, Written Description Requirements" 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). As there indicated, the written description requirement for a claimed genus can be satisfied in a number of <u>alternative</u> ways, such as through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

The Examiner asserts that the specification teaches the structure of only a few representative species of such polynucleotides (SEQ ID NO: 1, 3 . . . 45). Applicants strongly disagree that the structure of <u>twenty-three</u> polynucleotides as set forth in SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, and 45 should be considered as representing only a few polynucleotides. The twenty-three polynucleotides are further characterized as each encoding a protein with metA activity. Applicants urge that twenty-three

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polynucleotides encoding a protein with metA activity constitutes a representative number of species, particularly considering that the claims as amended recite production of L-methionine.

Furthermore, Example 18 of the "Synopsis of Application of Written Description Guidelines" is particularly relevant, since the claims of the present invention are drawn to methods and not to polynucleotides. The claims in Example 18 relate to a method of producing a protein and are drawn to a genus, i.e. any of a number of methods that can be used for expressing protein in mitochondria of the organism. Furthermore the recitation of a specific nucleic acid was not essential to the method. There was actual reduction to practice of a single embodiment, and there was no substantial variation within the claimed genus because there are a limited number of ways to practice the process steps.

Similarly, the present specification describes production of L-methionine by fermenting coryneform bacteria expressing a nucleotide sequence which encodes a protein with metA activity. The present specification also describes an embodiment of the method in which a further gene in the L-methionine biosynthetic pathway is overexpressed or mutated. Additionally, as in Example 18 of the Guidelines, the present specification provides an actual reduction to practice of the method as shown in Example 8. In Example 8, clones, which comprise a nucleotide sequence encoding the protein with metA activity and an additional mutated gene in the L-methionine biosynthetic pathway, were cultured in fermentation, and the desired production of the protein resulted. That process is the same irrespective of the selection of the polynucleotide sequence encoding a metA protein or of the gene in the pathway. As in Example 18 of the Guidelines, the present claims are adequately described.

The Examine also alleges that the specification fails to describe all such genes or all methods of reducing expression (see Office Action page 6). In response, in addition to the above remarks, there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). As pointed out above, the present specification shows a representative number of species having metA activity, and establishes a connection between a corenyform bacteria containing such a gene and production of L-methionine.

For these reasons, it is submitted that the claims as amended are in compliance with the written description requirement. Reconsideration and withdrawal of this rejection is respectfully requested.

#### Enablement Rejection

The Examiner asserts that the specification does not provide enablement for producing any sulfur containing chemical using any microorganisms expressing any polynucleotide encoding metA protein. In response, the present claims call for production of L-methionine.

Also, the claims (both amended and new) recite <u>coryneform</u> bacteria and not any microorganism. Furthermore, the specification and the Examples have shown that expression of a metA protein in a coryneform bacteria increases L-methionine. (See, for example, Example 8 at pages 37-38).

The disclosure is not limited to a few polynucleotides (see Office Action page 8 lines 3-4), but rather discloses twenty-three exemplary polynucleotides workable in the claimed process. This extensive disclosure provides guidance for the skilled artisan to practice the process as claimed.

For these reasons, withdrawal of this rejection is respectfully requested.

#### Rejections under 35 U.S.C. § 102(b)

Claims 1-3, 5-6, 7-12, and 14 were rejected as being anticipated by Bathe et al. (US 2002/0110877, hereinafter "Bathe"). Applicants respectfully traverse.

The Examiner characterizes Bathe as teaching isolation of polynucleotide SEQ ID NO: 1 encoding metA protein of SEQ ID NO: 2 from Corynebacterium and expression of said metA gene. Applicants strongly disagree with the Examiner's characterization of Bathe. Bathe relates to polynucleotides and methods which relate to metE. SEQ ID NO: 1 and 2 of Bathe do not disclose a polynucleotide which encodes metA nor the metA protein as stated by the Examiner. Rather SEQ ID NO: 1 and 2 of Bathe relate to metE, a totally different enzyme. Moreover, metE and metA have different activities, different sequences, and catalyze different reactions. The metE gene encodes homocysteine methyltransferase I while the metA gene encodes homoserine

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O-acetyltransferase. Furthermore, the metA discussed in Bathe (see paragraph [0138] of Bathe)

was isolated from Corynebacterium glutamicum, not from any of the organisms listed in the

present invention (see specification page 2 line 24 through page 3 line 2, List I). Additionally,

the sequences of the present invention are different than the metA sequence from

Corynebacterium glutamicum discussed in Bathe (see specification page 2 line 24-26).

Because the sequences and methods disclosed in Bathe are different than those in the

present invention, Bathe does not disclose every limitation of the claims. Therefore, Bathe does

not anticipate the claims. Reconsideration and withdrawal of this rejection is respectfully

requested.

Conclusion

For at least the above reasons, Applicants respectfully request withdrawal of the

rejections and allowance of the claims.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or

more divisional applications, if necessary.

Accompanying this response is a Petition for a three-month extension of time to and

including November 6, 2006 pursuant to 37 CFR § 1.7, to respond to the Office Action mailed

May 4, 2006 with the required fee authorization for the extension and extra claim fees. No

further fees are believed due. If any additional fee is due, the Director is hereby authorized to

charge our Deposit Account No. 03-2775, under Order No. 13111-00002-US from which the

undersigned is authorized to draw.

Respectfully submitted,

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